

Application No.: 10/809,975
Filing Date: March 26, 2004

REMARKS

Claims 1 and 7 have been amended to incorporate limitations previously found in Claim 5. Claim 5 has been canceled. Claim 7 has also been amended to recite that the muscarinic receptor test compound is a selective muscarinic receptor test compound. New Claims 14-18 have been added, the support for which may be found in the specification, for example, in paragraphs 0027-0031. No new matter has been introduced.

Claims 1-4, 6-11, and 14-18 are pending. The Applicants have carefully considered all of the Examiner's rejections, but respectfully submit that the claims are allowable for at least the following reasons.

Rejections under § 103

The Examiner rejected Claims 1-4 and 6-11 under 35 U.S.C. § 103(a) as allegedly being obvious over Lavand'homme et al. (Anesthesiology, 1999, 91, 1455-61) in view of Skjaerback et al. (U.S. Application Publication No. 2003/0176418) and Mitchell (J. of Pain and Symptom Management, Vol. 21, 5, May 2001). Lavand'homme discloses that the non-selective muscarinic agonist bethanechol is effective against allodynia. Skjaerback discloses the compound of formula IX as a muscarinic agonist and teaches that it can be used to treat "pain." Mitchell discloses that neuropathic pain symptoms can include allodynia and hyperalgesia.

As a first matter, the Applicants would like to point out that Skjaerback is assigned to the same assignee as the current application and was not published until after the effective filing date of the current application. Specifically, Skjaerback published on September 18, 2003. The current application claims priority to U.S. Provisional Application No. 60/459,045, filed on March 28, 2003. As such, Skjaerback cannot be used as prior art under 35 U.S.C. § 103(a) against the instant application. *See* 35 U.S.C. § 103(c)(1) ("Subject matter developed by another person, which qualifies as prior art only under one or more of subsections (e), (f), and (g) of section 102 of this title, shall not preclude the patentability under this section where the subject matter and the claimed invention were, at the time the claimed invention was made, owned by the same person or subject to an obligation of assignment to the same person."); *see also* M.P.E.P. § 2146. Accordingly, the Applicants respectfully submit that the elected species, directed to use of formula IX, is patentable.

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Furthermore, the Applicants respectfully submit that none the cited art render obvious the broader scope of Claims 1 and 7. Claim 1 recites treating neuropathic pain without alleviating acute pain using a selective M(1) activator. Similarly, Claim 7 recites identifying a selective muscarinic compound that alleviates hyperalgesia or allodynia without alleviating acute pain by using a muscarinic receptor test compound. As the Examiner recognized in the Office Action, none of the cited references mentioned above (including Skjaerback) disclose that compounds having activity at muscarinic receptors, such as the compound of formula IX, can be used to treat neuropathic pain without alleviating acute pain. The Examiner further cites Baker et al. (U.S. Patent No. 5,242,927); however, Baker only discloses that muscarinic agonists may be used to treat painful conditions such as rheumatism, arthritis, and terminal illness and does not disclose treating neuropathic pain without alleviating acute pain. In addition, nothing in Baker suggests the compounds disclosed therein are selective muscarinic agonists. Thus, none of the cited art teach or suggest all limitations of the pending claims.

The Applicants have surprisingly discovered that certain compounds having selective activity at muscarinic receptors have the unique property of being effective at treating neuropathic pain while at the same time not alleviating acute pain. Thus, Applicants are the first to discover an important new indication for these compounds (*i.e.*, selectively alleviating neuropathic pain without alleviating acute pain). None of the cited art discloses the treatment of this indication. As such, the Applicants respectfully submit that Claims 1-4 and 6-11 as well as new Claims 14-18, which depend from Claim 1, are not obvious.

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, the Applicants are not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. The Applicants reserve the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history

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shall not reasonably infer that the Applicants have made any disclaimers or disavowals of any subject matter supported by the present application.

Please charge any fees, including any fees for extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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